

REMARKS

Claims 9-16 were pending in the application. Claim 14 is cancelled without prejudice or disclaimer. Hence, claims 9-13 and 15-16 are pending.

The claims are objected to. Claims 9-13 are rejected under 35 U.S.C. §102(b). Further, pending claims 9-13 and 15-16 are rejected under 35 U.S.C. §103(a). Applicants address these objections and rejections below.

I. OBJECTIONS TO THE CLAIMS:

The Examiner has objected to claims 9-15 for various informalities as discussed on page 2 of the present Office Action. In particular, the Examiner has objected to claim 9 for allegedly being unclear as to whether the first optical fibre in claim 9 is intended to have only one of the light sources adjacent its proximal end. Office Action (9/24/2008), page 2. Applicants kindly inform the Examiner that the first optical fibre can have one of the light sources adjacent its proximal end as clearly claimed as well as clearly described at least in part on page 8, lines 1-9 of Applicants' Specification which discusses a Y-coupler connecting the optical fibres with a single optical fibre.

Further, the Examiner has objected to claims 15 and 16 for various typographical errors. Office Action (9/24/2008), page 2. As indicated above, Applicants amended claims 15 and 16 to correct these typographical mistakes. The amendments made to claims 15 and 16 were not to overcome prior art. Hence, no prosecution history estoppel arises from the amendments to claims 15 and 16. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 U.S.P.Q.2d 1705, 1711-12 (2002); 56 U.S.P.Q.2d 1865, 1870 (Fed. Cir. 2000). Further, the amendments made to claims 15 and 16 were not made for a substantial reason related to patentability and therefore no prosecution history estoppel arises from such amendments. See *Festo Corp.*, 62 U.S.P.Q.2d 1705 at 1707 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 41 U.S.P.Q.2d 1865, 1873 (1997).

As a result of the above, Applicants respectfully request the Examiner to withdraw the objections to the claims.

II. REJECTIONS UNDER 35 U.S.C. §102(b):

The Examiner has rejected claims 9-13 under 35 U.S.C. §102(b) as being anticipated by Keller et al. (WO 02/07592) (hereinafter "Keller"). Office Action (9/24/2008), page 2.

For a claim to be anticipated under 35 U.S.C. §102, each and every claim limitation must be found within the cited prior art reference and arranged as required by the claim. M.P.E.P. §2131.

As indicated above, claim 9 was amended to include the limitations of claim 14, which includes the aspect of having the apparatus include a cranial access bolt for insertion into the skull of the patient, and means for supporting the optical fibres in the access bolt. The Examiner admits that Keller does not disclose the aspect of an apparatus including a cranial access bolt for insertion into the skull of the patient, and means for supporting the optical fibres in the access bolt. Office Action (9/24/2008), page 4. Thus, Keller does not disclose all of the limitations of claim 9, and thus Keller does not anticipate claim 9. M.P.E.P. §2131.

Claims 10-13 each recite combinations of features of independent claim 9, and hence claims 10-13 are not anticipated by Keller for at least the above-stated reasons that claim 9 is not anticipated by Keller.

Applicants respectfully assert that not each and every claim limitation was found within Keller, and thus claims 9-13 are not anticipated by Keller. M.P.E.P. §2131.

III. REJECTIONS UNDER 35 U.S.C. §103(a):

The Examiner has rejected claims 14-16 under 35 U.S.C. §103(a) as being unpatentable over Keller in view of Miller et al. (U.S. Patent No. 5,579,774) (hereinafter "Miller"). The Examiner has further rejected claims 9-16 under 35 U.S.C. §103(a) as being unpatentable over Miller in view of Keller.

Claim 14 is cancelled without prejudice or disclaimer. Hence, the rejections to claim 14 are moot.

With respect to pending claims 9-13 and 15-16, Applicants respectfully traverse these rejections for at least the reasons stated below and respectfully request the Examiner to reconsider and withdraw these rejections.

A. Claims 15-16 are patentable over Keller in view of Miller.

Most if not all inventions arise from a combination of old elements. *See In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Therefore, an Examiner may often find every element of a claimed invention in the prior art. *Id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See Id.* In order to establish a *prima facie* case of obviousness, the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998). The Examiner must provide articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited approvingly in *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007)).

As understood by Applicants, the Examiner admits that Keller does not teach "wherein the apparatus additionally comprises a cranial access bolt for insertion into the skull of the patient, and means for supporting the said optical fibres in the access bolt, such that light from the said light sources is directed towards the surface of the brain, thereby enabling measurement of the oxygen saturation level of blood at the brain surface" as recited in claim 9. Office Action (9/24/2008), page 4. The Examiner asserts that Miller teach these missing claim limitations. *Id.* The Examiner's reasoning for modifying Keller with Miller to include the above-cited claim limitations is "since it would stabilize and secure the apparatus for accurate placement of the apparatus within the internal measurement site and also maintain intracranial sterility." *Id.*

The proposed modification to Keller of including a cranial access bolt for insertion into the skull of the patient, and means for supporting the optical fibres in the access bolt, such that light from the light sources is directed towards the surface of the brain, thereby enabling measurement of the oxygen saturation level of blood at the brain surface, would change the principle of operation of Keller.

Keller describes an apparatus in which the optical fibre feeds round the edge of the brain cavity. See Figure 9 of Keller. It is a large and invasive device and in order to position it correctly, it must enter through the skull at a shallow angle. This is best demonstrated by Figure 6 of Keller. The skilled person in the art would recognize that it is not practical, or even possible to change this device so that it can be inserted via a cranial bolt. A cranial bolt is positioned perpendicular to the skull surface and devices which are inserted into it are fed in that direction. Therefore, the device of Keller is entirely incompatible with having a cranial access bolt for insertion into the skull of the patient.

Consequently, the proposed modification would change the principle of operation of Keller. As a result, there is no suggestion or motivation to make the proposed modification. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Accordingly, the Examiner has not presented a *prima facie* case of obviousness in rejecting claims 9-13 and 15-16. M.P.E.P. §2143.

B. Claims 9-16 are patentable over Miller in view of Keller.

The Examiner asserts that Miller teaches all of the limitations of claim 9 except for the details of the oximetry probe, specifically a first monochromatic light source, a second monochromatic light source, a first and second optical fiber, a receiver, means for determining the oxygen saturation level of the blood and means for pulsing each light source. Office Action (9/24/2008), pages 4-5. Applicants respectfully traverse the assertion that Miller teaches an oximetry probe. Instead, Miller teaches a device for laser Doppler flowmetry. See, e.g., column 1, lines 9-12. Laser Doppler flowmetry is a technique that uses short optical wavelengths to detect low flow velocities out of the range of Doppler ultrasound. See http://en.wikipedia.org/wiki/Photoacoustic_Doppler_effect#Laser_doppler_flowmetr

y. Laser Doppler flowmetry is a technique limited by high background noise and low signal due to multiple scattering. *Id.* Laser Doppler flowmetry is not the same as an oximetry probe. Further, the teachings of Miller do not relate to the method of measuring cerebral blood flow.

As discussed above, the Examiner must provide articulated reasoning with some rational underpinning for modifying Miller, which teaches a device for laser Doppler flowmetry, to be replaced with an oximetry probe. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007). The Examiner has not provided any rationale as to why one skilled in the art would modify Miller to replace a device for laser Doppler flowmetry with a different device, an oximetry probe. Since the Examiner has not provided such required reasoning, the Examiner has not presented a *prima facie* case of obviousness for rejecting claims 9-13 and 15-16. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1396 (U.S. 2007); *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998).

IV. CONCLUSION:

As a result of the foregoing, it is asserted by Applicants that claims 9-13 and 15-16 in the Application are in condition for allowance, and Applicants respectfully request an allowance of such claims. Applicants respectfully request that the Examiner call Applicants' attorney at the below listed number if the Examiner believes that such a discussion would be helpful in resolving any remaining issues.

Respectfully submitted,

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